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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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22045	7590	02/18/2010	EXAMINER	
BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075			FLETCHER, JERRY-DARYL	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,306	Applicant(s) GOMO, OYSTEIN	
	Examiner JERRY-DARYL FLETCHER	Art Unit 3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7,10-13 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7,10-13 and 16-18 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 November 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a **FINAL OFFICE ACTION** in response to communications received on 11/18/2009. Claims 1, 3-4, 7 and 10 have been amended. Claims 2, 5-6, 8-9 and 14 have been cancelled. Claims 11-13 remain as previously presented, and claims 15-18 have been newly added. Claims 1, 3-4, 7, 10-13 and 15-18 are pending in the current application and are addressed below.

Response to Amendment

2. Applicant's amendments to the drawings are sufficient to overcome the objections set forth with respect to the drawings in the previous Office Action.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No: US 5,779,484 to Lampotang et al. (Lampotang), in view of US Patent No: US 3,662,076 to Gordon et al. (Gordon), and US 1,974,366 to Pollock (Pollock).

With Respect To Claims 1 and 3

Lampotang teaches a medical patient simulator for simulation comprising:
a torso containing at least one artificial lung and a sternum (col. 1, ll. 54-67 to col. 2, ll. 1-23 & Figure 9, element 818);
wherein bellows are used to actuate the lung motion (col. 16, ll. 27-40);

a chest skin placed at least partially on the outside of the torso (col. 26, ll. 41-44); lung bellows are used to simulate lung motion and further that these motions are coupled to the bellows through computerized controllers (col. 11, ll. 59-67 to col. 12, ll. 1-9) [claim 3].

Lampotang, however, fails to specifically teach a means for pulling down the chest skin providing an external visible depression of the skin below the sternum of the torso, or that the means includes a mechanism adapted to pull the chest skin in a synchronous fashion with the at least one lung raising and lowering the chest, or that the means further includes an elastic pulling strap attached to the inside of the skin approximately in the middle of the area where subcostal contractions occur, or that said means and said artificial lungs are coupled so that when said means are actuated to pull in the chest skin, said means and said lungs are adapted to move synchronously.

Gordon teaches a patient simulator for simulating subcostal retractions wherein the skin on the torso is moved in order to simulate breathing (col. 4, ll. 49-60).

Pollock teaches the use of an elastic strap on the inside of a dummy in order to pull the area where it is located to simulate skin movement (page 1, ll. 66-80).

It would have been obvious to one possessing ordinary skill in the art, at the time of the invention, to have combined the teachings of Lampotang and Gordon by providing the invention of Lampotang with the ability to simulate subcostal retractions, as taught by Gordon, in order to yield the predictable result of providing a medical patient simulator with the ability to simulate lower chest movement, as taught by Gordon. Furthermore, by substituting the push rods of Gordon with the elastic strap of

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Pollock in order to yield the predictable result of providing alternative movement componentry. It would have also been obvious to one of ordinary skill in the art, at the time of the invention, to have coupled the lung motion of Lampotang with the motion of the elastic strap in the modified Lampotang-Gordon-Pollock invention, in order to provide realistic simulation of the contraction and expansion of the torso of a patient.

5. Claims 4, 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang in view of US 4,932,879 to Ingenito et al. (Ingenito) and US 5,153,635 to Kahle et al. (Kahle).

With Respect To Claims 4 & 12

Lampotang teaches a medical patient simulator comprising:

a torso containing at least one lung (col. 6, ll. 23-32), with the option of altering the compliance of the at least one lung (col. 30, ll. 34-37), where the at least one lung is arranged between a first and second plate in the torso, the spacing of the plates being adjustable, the first plate being movable;

a pneumatically driven mechanism being adapted to force the first plate towards the second plate, the pneumatically driven mechanism including bellows (col. 16, ll. 42-46); and

a means for connecting the pneumatically driven mechanism to the second plate to provide the force between the first and second plate (col. 16, ll. 40-42).

Lampotang, however, fails to specifically teach that the means for connecting the pneumatically driven mechanism to the second plate is a flexible means wherein the

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flexible means is an elastic strap that has an initial slack so that the first plate is free to move relative to the second plate when the pneumatically driven mechanism is inactive [claim 12], or that one of the plates is fixed [claim 4].

Ingenito teaches a training manikin wherein a lung is disposed between a first and second plate in a torso, with the first plate being moveable relative to the torso, and the second plate being fixed relative to the torso (col. 14, ll. 53-68 to col. 15, ll. 1-2; Figures 7A, 7B) [claim 4].

The applicant admits that it is old and well known to use flexible and rigid connectors to transfer force from one body to another.

Kahle discloses that it is known to provide slack in elastic straps (col. 8, ll. 12-14).

By using the claimed flexible means or the rigid means as taught by Lampotang, the effect of providing the force between the plates is accomplished. It is therefore interpreted as a matter of design choice to use either option over the other since they both achieve the same desired result, as claimed by the applicant.

At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art, to have used either the flexible means as claimed by the applicant or the rigid means as taught by Lampotang since the choice of one over another is interpreted as a matter of design choice that fails to patentably distinguish the claimed invention from the prior art of Lampotang. Furthermore, by supplementing the teaching of Lampotang with a plate structure similar to the one taught by Ingenito, the base of the bellows would be situated on a fixed plate, and the top plate of Lampotang would be the moveable plate. Furthermore, by providing slack in

the strap, as taught by Kahle, would have been obvious to one of ordinary skill in the art in order to yield the predictable result of increasing the movement of the plates.

With Respect To Claims 11 & 13

The claimed invention recited in claims 11 and 13 are not patentably distinguishable from the claimed invention of claim 4 since in claim 13, the applicant clarifies that the "third and fourth plates" recited in claim 11, are the "first and second plates" recited in claim 4. For this reason, the examiner rejects the claims under the prior art applied to claim 4.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang in view of US Patent No: US 5,394,766 to Johnson et al. (Johnson) and US Patent No: US 6,336,047 to Thu et al. (Thu).

With Respect To Claim 7

Lampotang teaches a medical patient simulator comprising a torso (Figure 1) but fails to specifically teach that the torso also includes two air cushion actuators [claim 8] arranged on the right and left sides of the backside of the torso wherein the actuators are designed to be operated in at least a mode for simulation of normal muscle movement, alternate and regular activation of the simulators on the left and right sides; a mode for simulation of muscle spasms, rapid and irregular activation of the actuators on the left and right sides; or a mode for simulation of defibrillation, rapid activation of the actuators simultaneously, once for each defibrillation wherein the two actuators are

air cushions situated near the outer surface of the simulator to act between a rigid part of the simulator and a surface upon which the simulator is placed.

Johnson teaches the use of actuators on the left and right sides of the torso of a simulated patient ((Figure 1, elements 50 and 50').

Thu teaches the use of a manikin to simulate spasms, breathing and defibrillation (col. 3, ll. 23-40).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have combined the teachings of Lampotang, Johnson and Thu, to have used the actuators of Johnson to simulate the movements taught by Thu in a patient simulator as taught by Lampotang. This would constitute the combination of known components to achieve a desired result since, as taught by Johnson, the use of actuators in dummies is known, and as taught by Thu, the use of dummies/manikins to simulate motion is known.

The applicant admits that it is old and well known in the art to use air cushion actuators.

By using air cushion actuators as claimed by the applicant, or by using actuators as taught by the modified reference of Lampotang, Johnson and Thu, the effect of simulating the muscular motion is accomplished. Therefore, it is interpreted as a matter of design choice to choose to use the actuator assembly as claimed or the one taught by the modified reference of Lampotang, Johnson and Thu since the choice of using one over the other does not provide any significant utility.

At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art, to have used either the actuators as claimed by the applicant or the ones as taught by the modified reference of Lampotang, Johnson and Thu since the choice of one of the other is interpreted as a matter of design choice that fails to patentably distinguish the claimed invention from the prior art of record.

7. Claims 10, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang in view of US Patent No: US 4,003,141 to Le Roy (Le Roy), US Patent No: US 2,551,433 to Graves (Graves), and US Patent Application No: US 2004/0157199 to Eggert et al. (Eggert).

With Respect To Claims 10, 16-17

Lampotang teaches a medical patient simulator, in particular a simulator for simulation of an infant, comprising a head (Figure 1). Lampotang, however, fails to specifically teach a head having one or more air cushions in at least one fontanelle area on the head of the simulator, which air cushion(s) is/are designed to be filled with air in order to simulate an increased pressure in the brain and provide swelling in the fontanelle area.

Le Roy teaches an intracranial pressure monitoring device where a head has one or more air cushions (abnormal pressure creating means 30) (col. 4, line 7) also see (fig.2, element 30) in at least one fontanelle area on the head of the simulator, which air cushion(s) is/are designed to be filled with air in order to simulate an increased pressure

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in the brain (the supply of air or other suitable fluid through tube 36 creates a pressure in member 38) (col. 4, lines 16-17).

Graves teaches the use of a rubber cushion in the fontanelle area of a dummy that is situated between a rigid part of the dummy and a "skin" of the dummy (col. 5, ll. 3-14) [claim 16].

Eggert teaches the use of a manikin to simulate swelling (par. 0128).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have combined the teachings of Lampotang, Le Roy, Graves and Eggert, to have provided a head having one or more air cushions in at least one fontanelle area on the head of the simulator, which air cushion(s) is/are designed to be filled with air in order to simulate an increased pressure in the brain as taught by Le Roy for the purpose of enhancing the apparatus of Lampotang et al. for a more accurate simulation of the dynamic condition occurring in the body during a traumatic occurrence.

Furthermore, by using the manikin to indicate swelling, as taught by Eggert, the swelling of the fontanelle region can also be added to the invention in order to provide a realistic simulation with a graphic depiction of a swollen fontanelle area. By providing the cushion of Graves to the manikin of Lampotang, and further substituting the cushion of Graves with an air cushion, as taught by Le Roy, it would have enabled the user of the invention to easily identify the fontanelle area of an infant in the training of a midwife. It would also have been obvious to have used a mixture of air and rubber to have filled the depression in the fontanelle region, in order to provide the fontanelle region with a different texture to the rest of the head of the dummy [claim 17].

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8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lampotang, Ingenito and Kahle as applied to claim 4 above, and further in view of Gordon and Pollock.

With Respect To Claim 18

Lampotang, Ingenito and Kahle teach the limitations of claim 4 (see rejection of claim 4 above), but fail to specifically teach that the simulator further comprises a strap for pulling down the chest skin to provide an external visible depression of the chest skin below the sternum of the torso, wherein the strap is attached to the chest skin from the inside of the torso, and wherein the strap and the lung are coupled to move synchronously.

Gordon teaches a patient simulator for simulating subcostal retractions wherein the skin on the torso is moved in order to simulate breathing (col. 4, ll. 49-60).

Pollock teaches the use of an elastic strap on the inside of a dummy in order to pull the area where it is located to simulate skin movement (page 1, ll. 66-80).

It would have been obvious to one possessing ordinary skill in the art, at the time of the invention, to have combined the teachings of Lampotang and Gordon by providing the invention of Lampotang with the ability to simulate subcostal retractions, as taught by Gordon, in order to yield the predictable result of providing a medical patient simulator with the ability to simulate lower chest movement, as taught by Gordon. Furthermore, by substituting the push rods of Gordon with the elastic strap of Pollock in order to yield the predictable result of providing alternative movement componentry. It would have also been obvious to one of ordinary skill in the art, at the

time of the invention, to have coupled the lung motion of Lampotang with the motion of the elastic strap in the modified Lampotang-Gordon-Pollock invention, in order to provide realistic simulation of the contraction and expansion of the torso of a patient.

Allowable Subject Matter

9. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: In the instant case the applicant positively recites that a bellows is located between a chest plate that is hinged to a lever such that the chest plate, the bellows and the lever are adapted to move with the inflation and deflation of an artificial lung. This specific arrangement is neither taught, nor suitably suggested by the prior art of record. Specifically, prior art references of Lampotang, Gordon and Pollock, when combined as in the above rejection of claim 3, teach that the bellows, the chest plate and the lung are electronically coupled by the controllers of Lampotang. The prior art references, however, are silent as to the matter of the lever assembly, or how the lever assembly, coupled with the plate and the bellows are adapted to move with the inflation and deflation of the artificial lung.

Response to Arguments

11. Applicant's arguments filed 11/18/2009 have been fully considered but they are not persuasive. With respect to the arguments directed to the rejection of claim 1, it is noted that Gordon teaches that the movement occurs in the subcostal region of the

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manikin (Gordon: Figure 2, element 90: col. 4, ll. 49-54). Furthermore, newly applied prior art of Pollock teaches the use of the internal straps.

With respect to the arguments directed to the rejection of claim 4, it is noted that newly applied prior art of Kahle teaches that it is known to provide slack in elastic straps.

With respect to the arguments directed to the rejection of claim 7, it is noted that the rotacs of Johnson are placed at the back of the dummy, thus they would act between a rigid part of the dummy and a surface that the dummy was placed on. Furthermore, the prior art of Thu is used to teach that it is known to simulate muscle spasms breathing and defibrillation. The combination of Thu, Johnson and Lampotang teach the claimed invention and provide rationale apparent to one of ordinary skill in the art, as to how to combine the teachings to obviate the claimed invention.

With respect to the arguments directed to the rejection of claim 10, it is noted that newly applied prior art of Graves, when combined with the previously cited prior art references, teaches the claimed invention (see rejection of claim 10 above).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY-DARYL FLETCHER whose telephone number is (571)270-5054. The examiner can normally be reached on Monday to Friday 9:00 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan M. Thai can be reached on (571) 272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Kathleen Mosser/
Primary Examiner, Art Unit 3715

/J.D.F./
Examiner, Art Unit 3715